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## BIOTECHNOLOGY, FOOD, AND AGRICULTURE DISPUTES OR FOOD SAFETY AND INTERNATIONAL TRADE

*Shirley A. Coffield\**

### I. RECENT (GENETICALLY MODIFIED ORGANISMS (GMO)) ACTIVITIES

The United States and Canada have been united in their policies with respect to GMOs and have also, generally, been treated similarly by other countries with respect to requirements and restrictions associated with genetically modified foods.

#### A. Cartagena Protocol

The Cartagena Protocol on Biosafety to the Convention on Biological Diversity emerged from talks on January 24 – January 29, 2000, in Montreal at a meeting of the parties to the Convention on Biological Diversity sponsored by the United Nations.<sup>1</sup> The United States is not a member of the Biodiversity Agreement. However, they did attend the Convention with a delegation and worked with like-minded countries (making up the Miami Group), which included Canada, Chile, Argentina, Australia, and Uruguay, all countries that had been concerned, that a Protocol would have made trading in GMOs very difficult or impossible in some instances. While the Protocol as agreed to in January failed to open up trade in GMOs significantly, it does recognize that commodities/foods made from GMOs can be traded and did not include some of the worst-feared provisions that would have prohibited trade in genetically modified plants and animals, which had been the goal of a number of environmental groups. The key provisions of the Protocol follow:

The Preamble recognizes the risks and benefits associated with biotechnology and the need to protect biological diversity.<sup>2</sup> It emphasizes that

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\* Coffield bio.

<sup>1</sup> See Cartagena Protocol on Biosafety Home Page (visited July 25, 2000) <<http://www.biodiv.org/biosafe/Protocol/Index.html>>.

<sup>2</sup> Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Preamble, (stating that it is “[a]ware of the rapid expansion of modern biotechnology and the growing public concern over its potential adverse effects on biological diversity, taking also into account risks to human health”).

the Protocol “shall not be interpreted” as changing the rights and obligations of countries under other international pacts, such as the World Trade Organization.<sup>3</sup> The Preamble also recognizes that trade and environmental agreements should be mutually supportive and that the Protocol is not subordinate to other international pacts.<sup>4</sup> The Protocol establishes a Biosafety Clearing House for countries to share information about GMOs. Countries must inform the Clearing House within fifteen days of the approval of any crop varieties which could be used in food, animal feed, and processing.

Exporters are required to obtain an importing country’s approval, through a procedure known as advance informed agreement (AIA), for initial shipments of genetically modified organisms intended for release into the environment. Examples include seeds and trees.

GMOs intended for food, feed, and processing – in other words, commodities – are exempted from the AIA requirement. However, they must be labeled “may contain” GMOs and countries can decide whether to import those commodities based on a scientific risk assessment. Countries do not have complete “scientific certainty” to block imports of a GMO they fear could be harmful to biological diversity and, by extension, human health. Countries also may consider “socioeconomic factors,” such as the impact on local farmers, consistent with their other international obligations when making import decisions.

Negotiations on more detailed labeling requirements will be undertaken, with the requirement that they be completed no later than two years after the Protocol takes effect.

Exceptions to the AIA requirement are granted for GMOs intended for “contained use,” such as in research, and for GMOs in transit through a country.

GMOs used as pharmaceuticals for humans are exempted from the Protocol if they are addressed by other relevant international agreements or organizations.

Members of the pact will cooperate to help developing countries build human resources and institutions to make informed decisions about GMOs.

New negotiations will be launched to address the issue of liability for any damage resulting from the cross-border movements of GMOs. The goal is to finish in four years.

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<sup>3</sup> *Id.* (emphasizing that this Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements).

<sup>4</sup> *Id.* (“[r]ecognizing that trade and environment agreements should be mutually supportive with a view to achieving sustainable development” and “[u]nderstanding that the above recital is not intended to subordinate this Protocol to other international agreements”).

Countries have an obligation to inform affected parties and take other appropriate action if they discover an unintentional movement of GMOs across borders. If illegal shipments occur, the affected party can request the shipper to retrieve or destroy the GMO at its own expense.

The agreement has to be ratified by nations that are party to the 1992 U.N. Convention on Biological Diversity, and it goes into effect ninety days after the fiftieth country endorses it. Once implemented, there are five-year reviews. There is no time line on how long ratification can take, and it is expected to take up to two or more years. The Protocol will be open for signature beginning in mid-May, 2000. While it is possible that the end of 2000 could complete ratification, much will depend upon what happens in the next year on perceptions and scientific realities surrounding the use and effect of GMOs.

One area of confusion will most certainly be the role of the World Trade Organization (WTO) in the Protocol. While the Protocol does not give the WTO precedence, the Protocol is subject to "other international agreements." A WTO challenge is still possible if a nation does not have adequate grounds for refusing to admit GMOs. Both the United States and Canada have a major interest in GMO trade, particularly with respect to E.U. restrictions on such trade, and the WTO option for challenging E.U. restrictions is a very real one for both countries.

## B. National Academy of Science (NAS) Report

As to the science of GMOs, we can expect to see a number of conflicting reports out of various governments which, unfortunately, may reflect government policies as much as scientific evidence speaking to the health risk of genetically modified foods. Most recently, in early April, the U.S. National Academy of Science issued a long-expected report on the health consequences of genetically modified food. That report found that there is no evidence or reason at this point to be concerned about eating genetically modified foods. The report found that the use of such food poses no human health risk. The report titled, *Genetically Modified Pest Protected Plants: Science and Regulation* was written by the National Academy's National Research Council and was released on April 5, 2000<sup>5</sup>. The NAS did make the important point that the safety of the food was dependent to a large extent on the strength of the U.S. system governing transgenic plants and called for even further strengthening of that system. It recommended that the government perform more extensive research on the effects to human health

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<sup>5</sup> See *Genetically Modified Pest Protected Plants: Science and Regulation* (visited Sept. 7, 2000) <<http://books.nap.edu/books/0309069300/html/1.htm>>.

in the environment, “so that the agencies will have a more refined scientific basis for making decisions,” especially in light of the increasing ubiquity of genetically engineered seeds. Looking at the available science, the NAS report stated, “no strict distinction exists between the health and environmental risks posed by plants genetically engineered through modern molecular techniques and those modified by conventional breeding practices.” The NAS report has been characterized by those both in the industry and those opposed to GMOs as “cautious.” An important recommendation made in the report, which highlights some of the issues we are discussing here today, is that the Environmental Protection Agency, the Food and Drug Administration, and the Department of Agriculture, which all have various regulatory and oversight responsibilities over genetically engineered crops, should better coordinate and define their regulatory roles. Other recommendations include monitoring by agencies of ecological impacts of pest-protected crops and providing a more open and accessible regulatory process.

### C. Organization for Economic Cooperation and Development (OECD) Meeting

Another ongoing effort is in the OECD, which sponsored a conference in Edinburgh in late February on the scientific and health aspects of genetically modified foods. As might have been expected with a conference of 400 participants from a variety of backgrounds, there was a wide divergence of views on whether and how to use genetically modified technologies in food and crop sectors.

With respect to food safety, two principal conclusions emerged: First, that, worldwide, many people are eating genetically modified foods with no adverse effects on human health having been reported in the peer-reviewed scientific literature. Emphasis was placed on North America and China as the two major areas in the world that depend more and more on genetically modified foods. Second, there could be, in theory, a long-term effect on human health that has not been detected because genetically modified foods have been available for less than ten years.

The principle concern expressed during the conference related less to food safety than to the broader question of why genetically modified (GM) food is being produced at all. While many developing country speakers argued that GM technology is an essential part of any plan to increase their ability to meet food production needs, many non-governmental organization (NGO) speakers from environmental groups in Europe and North America argued that there were other less harmful ways to solve world food shortages. The other major concern at the conference, apart from food safety, was the

potential environmental impact of GM crops, especially in the biodiversity-rich tropics. Conference recommendations included setting up an international forum to continue the process begun by the OECD Edinburgh conference, modeled after the Inter-governmental Panel on Climate Change (IPCC).

#### D. GMO Labeling

Labeling of GMO products is likely to be the most contentious issue for many countries in the near future. For example, most recently, the Japanese Ministry of Agriculture published a distribution manual on bulk imported U.S. and Canadian grown genetically modified soy beans and corn – calling for extensive, detailed, voluntary management and verification for GM and GM-free foods. These guidelines are intended for U.S. and Canadian soy bean and corn growers, elevator operators, freight operators, and shippers, as well as their counterparts in the transportation cycle in Japan, including port service operators, transporters, warehousemen, distributors, and retailers.

The guidelines will be implemented as of April 1, 2001 as the Japan Agriculture Standard Quality and Content Labeling System on GM and GM-free foods. There are three labeling methods provided: One, for GM-free soy beans and corn where voluntary labeling as “GM-free” can be used; two for using soy beans and corn that are not sorted as GM-free and GM, where they must be labeled as “Not GM Sorted”; and three, when GM crops are used, where the product must be labeled as “Using Sorted GM” or “GM-based Products.” There are twenty-four products covered by the guidelines, including several types of tofu, foods that use soy beans as ingredients, edamame, green soy beans, corn snacks, corn starch, popcorn, frozen corn, canned corn, corn flour, corn grits, but excluding corn flakes and other corn-based foods.

The guidelines mandate that all parties, from growers to food makers, take appropriate measures to ensure that GM crops imported in bulk are not mixed with GM-free crops at every level from production to distribution, verified in written form. The guidelines apply to bulk-transported corn and soybeans only. For non-bulk soybeans and corn, such as tofu, miso, and corn snacks, the manual applies to the period until containers have been sealed and re-opened. The guidelines set an allowance of up to five percent for GM-free product handlers. This means they can use GM-free labeling if ninety-five percent of the soy beans or corn used is GM-free corn and soy beans and five percent was GM or GM-unsorted crops. Because of the possibility of mixing and distribution processes, consumer groups have strongly opposed this five percent allowance. In contrast, U.S. has looked at the five percent allowance favorably and Canadian growers and elevator operators who

believe they can comply with the multi-level layered verification requirement so long as there is a reasonable tolerance policy (generally considered to be over three percent).

The guidelines require certificates at each level of the process that is from growers through distributors. Certificates must be provided to the next level with each transfer. Copies of the certificates must be handed like a chain and without interruption from one level to another. The certificates must be kept for two years under reasonable safekeeping procedures. U.S. and Canadian farmers who want to use GM-free labeling must examine seeds with seed certificates and names and numbers, must examine to ensure crops are not blended with others, must use farming instruments exclusively for GM-free crops, and must clean these instruments between use if the instruments have been used for GM crops. The category requirements are similar for elevator operators, which must record seed names and numbers, shipment quantities, shipment dates, crop collection details, etc. Export elevators and operators have similar requirements.

Once the U.S. and Canadian soybeans and corn arrive at Japanese ports, the port operators must have clean facilities and equipment before unloading the cargo and they must also keep records. Wholesalers must operate in the same way. For example, processors in grits and starch factories must first test-run equipment to make sure that there is no leftover from previous operations and perform cleaning and keep separate storage space for GM-free foods. They also must keep records of deliveries and other details, and issue certificates. Food makers and distributors must confirm with certificates that ingredients are GM-free, keep their ingredients separate from GM-unsorted and clean facilities if they are not exclusively GM-free. They also must keep records of purchase, production, and other details. While this sounds extremely complicated, both U.S. and Canadian growers have indicated they can live with this restriction, primarily due to the five percent tolerance level, and they expect a limited possibility of violations on labeling.

In both the United States and Canada, mandatory GMO labeling is only required when there have been significant nutritional changes, the product is considered to be a different product, or to alert consumers of possible safety concerns, such as the presence of food allergens. In Canada, there is an ongoing public and private sector process to develop voluntary labeling standards for foods derived from biotechnology. The voluntary labeling project consists of a large number of Canadian industries such as the grocery business including distributors, industry representatives, and the Standards Board. The voluntary label will be akin to the organic label now allowed on a voluntary basis. It is expected that the process to develop the voluntary standard and voluntary labeling will probably take another year.

## E. U.S. Regulatory System for GMOs

In the United States, there is a multi-faceted system to insure that agricultural biotechnology products are safe for the environment and to animal and human health. The various responsible agencies act independently but have a relatively close working relationship. However, as noted in the NAS report, better coordination and less overlap would significantly improve the current system. To summarize the current system:

The United States Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) is responsible for protecting American agriculture against pests and diseases. The agency regulates the field-testing of genetically engineered plants and certain microorganisms. APHIS also approves and licenses veterinary biological substances, including animal vaccines that may be the product of biotechnology. USDA's Food Safety and Inspection Service (FSIS) ensures the safety of meat and poultry consumed as food. The Department of Health and Human Services' Food and Drug Administration (FDA) governs the safety and labeling of drugs and the nation's food and feed supply, including meat and poultry. The Environmental Protection Agency (EPA) ensures the safety and safe use of pesticides and herbicidal substances in the environment and for certain industrial uses of microbes in the environment.

The Department of Health and Human Service's National Institutes of Health have developed guidelines for the laboratory use of genetically engineered organisms. While these guidelines are generally voluntary, they are mandatory for any research conducted under Federal grants and they are widely followed by academic and industrial scientists around the world.

APHIS is the government's lead agency regulating the safe testing, under controlled circumstances, of biotechnology-derived new plant varieties. A company, academic institution, research institution, non-profit organization, or public sector scientist wishing to field test or move a biotechnology-derived plant must generally obtain APHIS approval before proceeding.

Applicants ask APHIS for permission to allow field testing (environmental release). They provide information about the plant, including all new genes and gene products, their origin, the purpose of the test, how the test will be conducted, and specific precautions to be taken to prevent the escape of pollen, plants, or plant parts from the field test site. An APHIS scientific reviewer evaluates the possible environmental impacts of the proposed field test. The possible impact of new plant varieties on endangered or threatened species is considered. Non-target species, those not meant to be directly impacted by the new plant, are also taken into account.



If testing is approved, APHIS personnel and state agriculture officials may inspect the field test site before, during, or after the test to ensure that it is conducted and managed safely.

Generally, before a genetically engineered crop can be produced on a wider scale and sold commercially, its creators must petition APHIS for a “determination of non-regulated status,”<sup>6</sup> which requires the submission of more information than a field test permit request. APHIS must be provided scientific details about the genetics of the plant, the nature and origin of the genetic material used, information about indirect effects on other plants, field test reports, and all information unfavorable to the petition. All petitions are published in the Federal Register and the public is given time to comment. APHIS grants the petition only if it determines that the plant poses no significant risk to other plants in the environment and is as safe to use as more traditional varieties.

Authorizations are also required for the movement into the United States or between states of any genetically engineered organism that is a potential plant pest. And, some developers of the very few biotech plants that are not regulated by APHIS may seek a voluntary courtesy permit, which may make it easier to move or field test the plant.

With APHIS approval, over 5000 field trials have been safely conducted since 1987. About forty new agricultural products have completed all the federal regulatory requirements (from all relevant agencies) and may be sold commercially. They range from longer-lasting tomatoes to pest-resistant corn.

USDA’s Economic Research Service (ERS) recently released the first government data on acreage of biotechnology-derived crops. The ERS report indicates that biotech soybean, cotton, and corn acreages have increased dramatically since the introduction of these crops in the mid-1990s.<sup>7</sup> They accounted for twenty to forty-four percent of acreage planted in 1998.

Environmental Protection Agency (EPA): The EPA approves new herbicidal and pesticide substances. The Agency also issues permits for large-scale testing of herbicides and biotechnology-derived plants containing new pesticide substances. In deciding whether to register a new pesticide, the EPA considers human safety, the fate of the substance in the environment,

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<sup>6</sup> This is a determination by APHIS that the new plant should be treated like any other plant and, therefore, may be grown, tested, or used for traditional crop breeding without any additional APHIS action. Essentially, this determination permits the plant to be widely grown and commercialized.

<sup>7</sup> See Economic Research Service (visited July 24, 2000) <<http://www.ers.usda.gov/whatsnew/issues/biotech>>.

the safety for humans, its effectiveness on the target pest, and any effects on other, so-called “non-target” species.

**Food and Drug Administration (FDA):** The FDA ensures that foods derived from new plant varieties are safe to eat, holding them to the same high standard of safety as any more traditional food product.

**Labeling:** Legal authority for food labeling rests with the Food and Drug Administration. Foods derived from biotechnology currently must be labeled only if they differ significantly from their conventional counterparts—for example, if their nutritional content or potential to cause allergic reactions is altered.

## II. TRADE AGREEMENTS: FOOD SAFETY

### A. North American Free Trade Agreement (NAFTA)

NAFTA provisions on sanitary and phytosanitary (S&P) measures are found in Chapter Seven of the NAFTA. The sanitary and phytosanitary measures provisions of the NAFTA include the first comprehensive agreements on S&P measures concluded by the United States. Before the NAFTA, rules on S&P measures had not been fully elaborated, although they were covered by the General Agreement on Tariffs and Trade (GATT) system at that time and some particular obligations were set out in Chapter Seven of the U.S.-Canada Free Trade Agreement. Prior to the NAFTA negotiations, a text on S&P measures had been proposed in the context of the Uruguay Round. The proposed text had been the subject of multi-lateral negotiations, but final agreement on the Uruguay Round had not been reached when NAFTA was concluded. The NAFTA provisions on S&P, therefore, drew from the Uruguay Round text as well as from other GATT texts and the U.S.-Canada Free Trade Agreement. However, because the NAFTA negotiations involved only three countries, the governments were able to tailor the NAFTA provisions to their particular needs.

Importantly, the NAFTA recognizes the right of the NAFTA governments, which include state and local governments, to adopt, maintain, or apply S&P measures, including measures more stringent than the international standard. Each government may establish levels of protection of human, animal, and plant life or health that the government considers to be appropriate. Article 712 of the NAFTA sets out three fundamental tests for S&P measures used to achieve the levels of protection that government considers appropriate. First, it requires that all S&P measures be based on scientific principles. Second, it requires that S&P measures not be

maintained where there is no longer a scientific basis for them. Third, it requires that S&P measures be based on a risk assessment as appropriate to the circumstances to assess whether a particular product, including a process or production method, or substance, in fact poses any risk. Once there is a determination that it is appropriate to protect human, animal, or plant life and health, the level of protection is up to the government. The United States interprets this language to protect the Delaney Clauses in U.S. legislation that set a zero tolerance for substances that have been determined to have a risk of causing cancer.<sup>8</sup>

The other fundamental requirements and obligations of the S&P agreement include provisions to assure that measures are nondiscriminatory and are not disguised obstacles to trade. Furthermore, Article 712 requires that sanitary or phytosanitary measures that a NAFTA government adopts or maintains must be applied only to the extent necessary to achieve the appropriate level of protection and cannot be used as a disguised restriction on trade. There is, however, no “least restrictive” obligation in this provision of the S&P chapter.

Recognizing that the S&P measures of the three countries are often different, Article 713 provides for the use of relevant international standards as a basis for each NAFTA government’s own measures. The objective is to make the NAFTA government’s measure equivalent or, where appropriate, identical in order to facilitate trade. There is, however, a recognition that there is to be no “downward harmonization” of S&P measures. International standards are a basis, but they are not the only basis for S&P measures. The international standards or guidelines or recommendations are defined as the Codex Alimentarius<sup>9</sup>, International Office of Epizootics, and Secretariat of the International Plant Protection Convention. The NAFTA governments also can designate other additional international organizations. An important consequence of these provisions is a sanitary or phytosanitary measure that conforms to a relevant international standard guideline or recommendation, presumed to be consistent with the basic obligations in the NAFTA. Accordingly, a NAFTA government challenging such a measure would have the burden of rebutting the presumption. However, if a measure differs from a relevant international standard, it does not necessarily create an adverse presumption although governments can request another government using such a standard to provide, in writing, the reason that a measure is not based

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<sup>8</sup> See Delaney Clauses in the Food Quality Protection Act of 1996, Pub. L. No. 104-170 § 405, 110 Stat. 1489 (1996).

<sup>9</sup> UNITED NATIONS, FOOD AND AGRICULTURE ORGANIZATION, UNDERSTANDING THE CODEX ALIMENTARIUS. FAO/WWO(1999) (visited Oct. 23, 2000) <<http://www.fao.org/docrep/w9114e/w9114e0.htm>>.

on the international standard if the requesting government believes that the S&P measure is adversely affecting or may affect its exports.

The NAFTA also obligates the three countries to seek equivalents with respect to the S&P measures, considering their own actual or proposed government measures as well as international standards in reaching equivalency. A cooperative approach is encouraged. Parties are to make S&P measures equivalent, where practicable. A committee on sanitary and phytosanitary measures is established under Article 722, as are technical working groups.

## B. GATT/WTO SPS

The OECD describes the Uruguay Round SPS agreement, in the book *FOOD SAFETY AND QUALITY TRADE CONSIDERATIONS*.<sup>10</sup> Many of the SPS agreement provisions have already been discussed in the context of the NAFTA. Both the United States and Canada have the option of using the WTO dispute settlement provisions in connection with disputes. That publication also describes the Codex Alimentarius provisions and procedures.

Mr. Frechette will be discussing the management of disputes in the context of the dispute-settlement mechanisms of both the WTO and the NAFTA.

## III. CURRENT CROSS BORDER ISSUES

I want to focus now on the specific kinds of issues and complaints that might arise in the context of the U.S.-Canada relationship, primarily as a result of differing operations and perceptions in the food safety area.

### A. U.S. Regulatory System Overview

First, it is important to note that, for the most part, the United States and Canada have a harmonious and compatible set of goals and policies on food safety and GMOs.

I will briefly give you an outline of the way the United States operates in regulating food safety issues. Our next presenter, Mr. Frechette, will be discussing the Canadian system.

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<sup>10</sup> ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT, *FOOD SAFETY AND QUALITY: TRADE CONSIDERATIONS* (1999).

Principal federal regulatory organizations responsible for providing consumer protection are the Department of Health and Human Services' (DHHS) Food and Drug Administration (FDA), the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS), Animal and Plant Health Inspection Service (APHIS), and the Environmental Protection Agency (EPA). The Department of Treasury's Customs Service assists the regulatory authorities by checking and occasionally detaining imports based on provided guidance. Many agencies and offices have food safety missions within their research, education, prevention, surveillance, standard-setting, and/or outbreak response activities, including DHHS's Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH); USDA's Agricultural Research Service (ARS); Cooperative State Research, Education, and Extension Service (CSREES); Agricultural Marketing Service (AMS); Economic Research Service (ERS); Grain Inspection, Packers and Stockyard Administration (GIPSA); the U.S. Codex office; and the Department of Commerce's National Marine Fisheries Service (NMFS).

The FDA is charged with protecting consumers against impure, unsafe, and fraudulently labeled food other than in areas regulated by FSIS. FSIS has the responsibility for ensuring that meat, poultry, and egg products are safe, wholesome, and accurately labeled. The mission of the EPA includes protecting public health and the environment from risks in the United States if it contains a food additive or drug residue not permitted by the FDA or a pesticide residue without an EPA tolerance or if the residue is in excess of an established tolerance. The primary role of the APHIS in the U.S. food safety network of agencies is to protect against plant and animal pests and diseases. The FDA, the APHIS, the FSIS, and the EPA also use existing food safety and environmental laws to regulate plants, animals, and foods that are the results of biotechnology.

## B. Laws and Implementing Regulations

The three branches of U.S. government, legislative, executive, and judicial, all have roles to ensure the safety of the U.S. food supply. Congress enacts statutes designed to ensure the safety of the food supply and establish the nation's level of protection. The executive branch departments and agencies are responsible for implementation and may do so by promulgating regulations, which the United States publishes in the *Federal Register* and which are also electronically available. Characteristics of the U.S. food safety system are the separation of powers and science-based decision-making. Agency decisions under U.S. food safety laws can be appealed to the courts that are empowered to settle such disputes.

Food safety statutes enacted by Congress provide regulatory agencies with broad authority, but also set limits on regulatory actions. The statutes are drafted to achieve specific objectives. Food safety agencies then develop regulations that give specific direction and establish specific measures. When new technologies, products, or health risks must be addressed, agencies have the flexibility to revise or amend regulations generally without need for new legislation. Agencies are able to maintain their state-of-the-art scientific methods and analyses because changes of this type can be made at the administrative/technical level.

Major U.S. food safety authorizing statutes include the Federal Food, Drug, and Cosmetic Act (FFDCA),<sup>11</sup> the Federal Meat Inspection Act (FMIA),<sup>12</sup> the Poultry Products Inspection Act (PPIA),<sup>13</sup> the Egg Products Inspection Act (EPIA),<sup>14</sup> the Food Quality Protection Act (FQPA),<sup>15</sup> and the Public Health Services Act.<sup>16</sup>

Procedural statutes, which regulatory agencies must follow, include the Administrative Procedures Act (APA),<sup>17</sup> the Federal Advisory Committee Act (FACA),<sup>18</sup> and the Freedom of Information Act (FOIA).<sup>19</sup> The APA specifies requirements for rule making (i.e., the process by which federal agencies formulate, amend, or repeal a regulation and the process permitting any interested party to petition for the issuance, amendment, or repeal of a regulation). Substantive regulations promulgated by an agency under the APA have the force and effect of law. FACA requires that certain kinds of groups whose advice is relied upon by the government be chartered as advisory committees, that they be constituted to provide balance, to avoid a conflict of interest, and to hold committee meetings in public with an opportunity for comment from those outside the committee. The FOIA

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<sup>11</sup> Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. § 348(3)(A) (1994)).

<sup>12</sup> Federal Meat Inspection Act, Pub. L. No. 59-242, 34 Stat. 1260 (1967) (codified at 21 U.S.C. §§ 601-695 (1994)).

<sup>13</sup> Poultry Products Inspection Act, Pub. L. No. 85-172, 71 Stat. 441 (1957) (codified at 21 U.S.C. §§ 451-470 (1994)).

<sup>14</sup> Egg Products Inspection Act, Pub. L. No. 91-597, 84 Stat. 1620 (1970) (codified at 21 U.S.C. §§ 1031 *et seq.* (1994)).

<sup>15</sup> Food Quality Protection Act, Pub. L. No. 104-170, 110 Stat. 1489 (1996) (codified as amended in 7 U.S.C. § 136 and 21 U.S.C. § 346 (1994 & Supp. III 1997)).

<sup>16</sup> Public Health Service Act, 42 U.S.C. § 262 (1994).

<sup>17</sup> Administrative Procedures Act, 5 U.S.C.S. §§ 553(b), (c) (1999).

<sup>18</sup> Federal Advisory Committee Act, Pub. L. No. 92-463, 86 Stat. 770 (1972) (codified as amended at 5 U.S.C. app. §§ 1-15 (1994 & Supp. IV 1998)).

<sup>19</sup> Freedom of Information Act, Pub. L. No. 89-487, 80 Stat. 250 (1966) (codified as amended at 5 U.S.C. § 552 (1994 & Supp. IV 1998)).

provides the public with a statutory right to access federal agency information.

The various agencies involved and the various legislative mandates make the system fairly cumbersome and difficult to understand, thus setting up an inherent barrier to entry for foreign exporters unfamiliar with the U.S. system. Furthermore, the occasional disputes between the FDA and the FSIS over jurisdiction lead to inconsistent ways of handling food safety issues depending upon whether the product is considered to be regulated by the USDA, the FSIS, the EPA, or by the FDA.

### C. Issues Creating Current and Potential Conflicts

Some specific issues between the United States and Canada reflect these different regulatory procedural approaches. These issues involve labeling, FDA issues, animal disease regulations, and pesticide regulations.

#### 1. FDA Hold and Test Rules

There have been several problems on the U.S.-Canada border involving FDA testing. FDA regulations require testing one percent of the imports. If tested, products must be held until the test results are in. In some instances, especially in the case of perishable foods, a product is held past its shelf life. The system is a logistical nightmare for exporters who frequently send trucks marked for testing back to Canada rather than risk losing the commercial value of the shipment. They then send a different truck on the theory that lightning does not strike the same shipper twice. This issue also highlights some inconsistencies between FDA procedures and USDA/APHIS regulations.

The United States and Canada are now working together to try to put a system in place that relies more on equivalency. The United States is reviewing the Canadian practices. The goal is to have the FDA allow more equivalency testing, thus limiting its testing to products most at risk, or possibly to less-frequent exporters to reduce testing of exporters with long problem-free records.

#### 2. Disease Issues with Respect to Swine and Cattle

In early 2000, Canada amended regulations to allow recognition of disease-free regions in the United States so that those regions would be able to ship to Canada. This is part of a larger obligation on the part of countries in the WTO to regionalize disease issues rather than restricting products from an entire country. With respect to cattle, Canada is working towards regulations to create three categories of levels of animal health risk by

region of the United States, allowing recognition of a region as either equivalent to Canada or as a lower or a higher risk. Some of the issues that involve potential problems in the United States have to do with state regulations since the states frequently are the ones that have in place regulations to determine that a state or area is free of brucellosis and tuberculosis.

### 3. Pesticide Regulations

With respect to pesticides, Canada and the United States are working with their industries to move towards harmonization of pesticide registration and tolerances. However, there is still a great deal of difference between the two countries with respect to the issue of pesticides. There are number of pesticides in use in Canada for which there are no registration or tolerances in the United States, which continues to be a cross-border point of contention. A particular crop protection product must be registered by a company in both countries for each crop and must have a tolerance level set for residues. The harmonization issues that are now being worked on by both governments include sharing information on what products are already registered in one country to speed up the process in the other. Companies with new pesticides are being encouraged to register them in both countries at the same time. As an incentive, the registration applications are treated on a priority basis if they are filed in both countries, which may cut as much as a year off the registration process.

An example of a particular problem that has been resolved involved canola seed in Canada, on which the chemical lindane was used. This problem was resolved at the end of 1999 when Canada voluntarily discontinued sales of lindane, which will be terminated by July of 2001, farmers forcing to use alternative products<sup>20</sup>. Producers of different commodities are preparing priority lists of pesticides they would like to see harmonized, and canola producers have been very active in this process. There is an ongoing cross-commodity initiative that, hopefully, will result in harmonization of pesticides used on commodities grown in both countries.

### 4. Meat Labeling

A potential area of conflict is proposed U.S. legislation requiring meat origin labeling. The U.S. National Cattlemen's Association has supported legislation that would require that imported and domestic meat products be labeled to inform the consumer of the country of origin of the livestock that

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<sup>20</sup> Lindane is used as an insecticide and has been proven dangerous because it has a long persistence in the environment and a tendency to bio-accumulate along food chains.



is the source of the meat and the meat products. The current rule is that large containers of meat or poultry products destined for further processing in the United States must have a country of origin mark; however, once the meat is further processed in the United States in an Agriculture Department-inspected meat or poultry plant, the USDA no longer requires labeling. Under NAFTA origin rules, beef products made from Canadian cattle slaughtered in the United States are considered to be of U.S. origin. To require a Canada origin mark would thus likely be considered a NAFTA violation. There continue to be increasing pressures from organizations pushing for more and more micro-labeling requirements with respect to country of origin on a number of food products, not only meat.

##### 5. Other Labeling Issues That Might Be Expected to Arise in the Future

The GMO issue that, although not currently a problem between Canada and the United States, could be an issue in the future as international rules become more precise, particularly since Canada is a member of the Biodiversity Agreement and the United States is not and, therefore, is not bound by any labeling requirements particular to that agreement.

Nutritional/health claims labeling raises other important issues. There are currently differing labeling requirements between the two countries with respect to nutritional labeling which has, as well, a food safety element. In the United States, there is mandatory labeling. In Canada, labeling is not mandatory, but if an entity decides to label, then certain things must be listed, and the label must be in English and French. The problem arises when entities wishing to sell into both the Canadian and U.S. markets have to label for the mandatory U.S. requirements, but that label does not meet Canadian requirements. The product then must have, in essence, three labels: a U.S. label, a Canadian label in French, and a Canadian label in English. Logistically, it can be very, very difficult if not impossible to create a label in three versions, and still meet the requirement in U.S. law that the label be "prominent" on a food package.

The Canadian government is currently working on a major revision of its rules, which will be either mandatory or voluntary. Health Canada, one of the Canadian food safety agencies, published some proposals a year ago outside the *Montreal Gazette* for industry and consumer comment and received a number of comments. The process has now been complicated by the fact that all health claims and nutrient content claims have been rolled into the issue of what to require on the label. The next proposal will be published in the *Montreal Gazette*, but possibly not for another one or two years.

Since the issues in Canada are all, individually, fairly important and controversial ones and there is a great deal of divergence between consumer

groups, such as the Center for Science in the Public Interest which has been pushing for mandatory labels, and industry sectors which prefer the voluntary approach or, if the labels are mandatory, they want different requirements. It is unlikely to be resolved soon. However, when these issues are resolved and assuming a mandatory label requirement goes into effect, it sets up another logistical problem for importers and exporters trying to access both the U.S. and Canadian markets. Labeling standards, depending upon how they are used, could be considered to be technical barriers to trade under the NAFTA and the WTO.

#### IV. THE US-CANADA MECHANISMS FOR IMPLEMENTING NAFTA GOALS AND RESOLVING DISPUTES SHORT OF FORMAL DISPUTE RESOLUTION

##### A. NAFTA

In the NAFTA, the Committee on Sanitary and Phytosanitary Measures facilitates the enhancement of food safety and sanitary conditions in the NAFTA area, promotes harmonization and equivalence of SPS measures, and facilitates technical cooperation and consultations. Under the NAFTA provision, this committee meets at least once a year. However, there are a number of technical working groups that meet more frequently, and the committee receives input from these groups, including the ones on fish and fish products, animal health, dairy, fruits and vegetables, and meat, poultry, and egg inspection. Issues such as certification requirements, labeling, equivalency, veterinary regimes, and disease issues come through these committees and are dealt with on a technical level by professionals in each country on a non-political basis. The non-political element is extremely important as two veterinarians sitting down are more likely to be able to reach the same conclusion than two politicians can on the same issue.

##### B. Canada/U.S. Agreement

The other primary conduit for the resolution of problems is in the U.S.-Canada Record of Understanding on Agricultural Trade<sup>21</sup> which was signed in 1998 and which establishes an ongoing process of consultation that emphasizes early identification of problems and effective cooperation to resolve them. A Consultative Committee on Agriculture (CCA) was

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<sup>21</sup> See Record of Understanding Between the Governments of Canada and the United States of America Regarding Areas of Agricultural Trade (visited Sept 11,2000) <<http://www.cfia-acia.agr.ca/english/corpaffr/international/record.html>>.

established which has met on a regular basis two to four times a year, generally in Washington or in Ottawa. One benefit of the CCA is that it is composed of both political level officers and trade policy officers from both the agriculture departments and the trade policy departments in the United States and Canada, that is the Foreign Agricultural Service and Agriculture and Agri-Food Canada and the Office of the U.S. Trade Representative and the Canadian Department of Foreign Affairs and International Trade. These political level officials then work with representatives that they have designated at the career level in the ministries and government agencies in connection with specific issues. The mandate of the CCA is to facilitate discussion and cooperation on matters related to agriculture, including specifically trade and market access, sanitary and phytosanitary issues, and cooperation in areas of mutual interest in agriculture, as well as in the other agriculture-related issues.

The CCA also established a Provincial State Advisory Group that represents provinces and U.S. states. The group consists of state officials and officials from the Canadian provinces that participate in the State/Provinces Agriculture Accord. This group provides a forum for producers and exporters to raise bilateral agricultural trade issues to enhance cooperation and coordination in areas of common concern. This group has been meeting regularly.

Finally, bilateral industry consultative groups have been established with representatives of private sector entities in Canadian and U.S. grains, livestock and red meat, and horticultural products groups. These consultative groups are established on an ad hoc basis, and representatives may participate in bilateral industry consultative groups at the invitation of the CCA chairs. These groups are intended to encourage the private sector to engage in cross-border dialog to increase mutual understanding and support the resolution of differences through consultation and discussion. The CCA also establishes, as necessary, particular working groups to handle specific issues between the two countries. The private sector mechanism has not been active as a formal group; industry representatives have been more active on their individual issues directly with government officials.

We can expect the issues of food safety, GMOs, labeling, and related issues to take up an increasing amount of time both internationally and bilaterally in the next few years. I expect that the international confusion on the issues of new technology in the food sector, the growing needs of developing countries, and the growing concern of environmental and consumer groups will lead to disputes and major economic and policy crises in major trading countries and trading blocs. The United States and Canada, generally in accord on these important issues, will need to cooperate and

**coordinate their activities in a more efficient and proactive way or risk losing the initiative on these important issues to other trading countries.**

